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FIRST NAMED INVENTOR ATTORNEY DOCKET NO.

09/051,034

APPLICATION NO.

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03/31/98

MCKENZIE

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3164.98USWO

HM22/1223

MERCHANT GOULD SMITH EDELL WELTER & SCHMIDT 3100 NORWEST CENTER MINNEAPOLIS MN 55402-4131

FILING DATE

EXAMINER

BRUNOVSKIS.P

ART UNIT PAPER NUMBER

10

1632 **DATE MAILED:**

12/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/051,034

Applicant(s)

McKenzie And Sandrin

Examiner

Peter Brunovskis

Group Art Unit 1632

Responsive to communication(s) filed on	•
☐ This action is FINAL.	
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.	
is longer, from the mailing date of this communication.	n is set to expire
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
	is/are allowed.
☐ Claim(s)	
	is/are objected to.
	are subject to restriction or election requirement.
Application Papers See the attached Notice of Draftsperson's Patent The drawing(s) filed on	is approved disapproved. aminer. priority under 35 U.S.C. § 119(a)-(d). copies of the priority documents have been
🔀 received in this national stage application	from the International Bureau (PCT Rule 17.2(a)).
*Certified copies not received:	
Acknowledgement is made of a claim for domes	stic priority under 35 U.S.C. § 119(e).
Attachment(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review Notice of Informal Patent Application, PTO-152	
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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-25, drawn to nucleic acids and methods of using said nucleic acids to produce cells for in situ or ex vivo gene therapy.

Group II, claim 22, drawn to transgenic animals and organs therefrom, every cell being modified by the nucleic acid of group I.

Note that claim 22 is generic to Groups I and II encompassing identical cells generated either from in vitro transfection or from the cells of transgenic organisms. The "organ" of claim 21 is interpreted as an organ with recombinant cells added or implanted via in situ or ex vivo gene therapy. Claim 22 will be examined to the extent that it reads on the elected invention and will require an amendment in accordance with this recitation.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Group I, directed to nucleic acids and methods of using said nucleic acids for production of cells for in situ or ex vivo gene therapy and Group II, directed to transgenic animals and organs therefrom containing said nucleic acids lack unity of invention because the products of each group have separate and distinct methods of use (gene therapy or organ transplants from transgenic animals) and modes of action and because 37 CFR 1.475(b) does not provide for multiple independent products. Furthermore, the methods of producing the inventions of Groups I and II (claimed and unclaimed, respectively) do not share special technical features in common and are materially different, since they are practiced with materially different process steps utilizing different reagents and different technical considerations.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Brunovskis whose telephone number is (703) 305-2471. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, can be reached at (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Peter Brunovskis, Ph.D. Patent Examiner Art Unit 1632

SCOTT D. PRIEBE, PH.D PRIMARY EXAMINER

Stott D. Priete